RNA Controlled Substance Monitoring Program Operating Manual

Controlled Substance Compliance Program

McKesson U.S. Pharmaceutical
Regulatory Affairs

Version Number	Date	Description
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APPENDICES:

1. Introduction

This manual ("Manual") is designed to be used by McKesson's Controlled Substance Monitoring Program Regulatory and Compliance organization ("Regulatory Affairs") as a guide to the Controlled Substance Monitoring Program ("CSMP") responsibilities of both the company and its employees, as they relate to the Retail National Account ("RNA") customer segment of McKesson's U.S. Pharmaceutical division ("U.S. Pharma"). This Manual includes comprehensive descriptions of various program components of the CSMP, or where issued, applicable standard operating procedures ("SOP") for the RNA customer segment ("RNA Customers").

As a DEA registrant, each of U.S. Pharma's distribution centers has regulatory responsibilities under controlled substances laws. Among other things, these laws and regulations create a closed system of distribution and require McKesson to provide effective controls and procedures to guard against theft and diversion of controlled substances. See 21 C.F.R. § 1301.71(a). They also require McKesson to operate a system that discloses suspicious orders of controlled substances, and to report suspicious orders to the DEA. See 21 C.F.R. § 1301.74(b).

McKesson's CSMP is designed to meet these regulatory requirements and applies to all distributions of controlled substances from U.S. Pharma. While all U.S. Pharma employees have an overarching responsibility for ensuring adherence to the CSMP and all controlled substances regulatory obligations, McKesson has a dedicated Regulatory Affairs team that has the primary responsibility for the administration of the program.

Further, the Regulatory Affairs team has a dedicated set of employees that has primary responsibility for the administration of the CSMP as it relates to RNA Customers ("RNA Regulatory Affairs"). Except as explicitly stated herein as generally applicable to the CSMP, the provisions of this Manual apply to the RNA Regulatory Affairs team and the RNA Customer segment (the term "Customers" herein refers to RNA Customers). Capitalized terms herein are defined in the main body of the Manual and/or Appendix D.

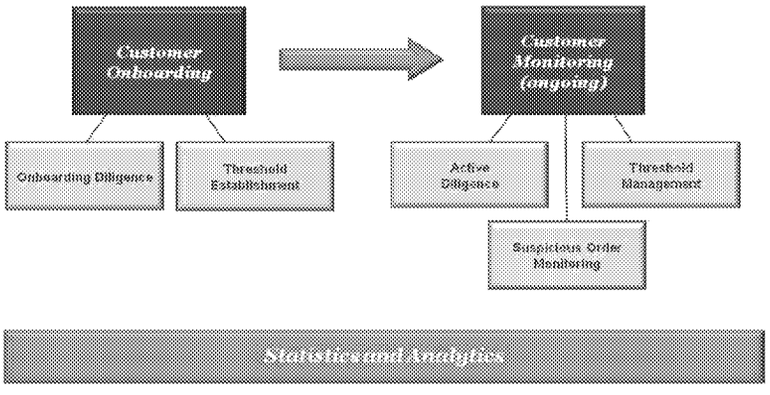
Note: Where certain customers share RNA Customer characteristics, while nonetheless having a unique business model, the RNA Regulatory Affairs team may, based on their professional judgment and expertise, conduct due diligence and otherwise review such customers in accordance with the SOPs contained in this Manual. Notwithstanding the preceding sentence, nothing herein requires that the RNA Regulatory Affairs team apply a particular SOP or all SOPs in this Manual to such customers.

CSMP Core Elements

The core elements of the CSMP are:

- Reviewing prospective customers and determining whether a prospective customer is eligible to purchase controlled substances;
- Monitoring customers' controlled substances purchases for orders that are suspicious, as defined by the regulations, and reporting these orders to the DEA;
- Blocking orders that have been reported to the DEA and not shipping them to the customer;
- Conducting initial due diligence on customers and reviewing customers on an ongoing and regular basis; and
- Determining when a customer is no longer eligible to purchase controlled substances.

CSMP Overview



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2. CSMP Mission Statement and Operating Principles

Our mission is to manage U.S Pharma's CSMP as a nationwide regulatory compliance program that is informed by diversion trends and our customers. Through our program, we strive to strengthen the understanding of the prescription drug abuse epidemic across the industry with dialogue and collaboration.

As we design and manage our program, we will adhere to the following operating principles:

- **Risk-based**: Comprehensively covers all controlled substances and all customers, while driving the greatest focus on those presenting a higher risk of diversion.

- **Uniform**: Generates consistent execution against nationwide standards and requirements.

- **Sustainable**: Achievable over the long-term.

- **Contemporary**: Refreshed on an ongoing basis to address current diversion trends, while reflecting the legitimate business models of our customers as they evolve.

- **Defined**: Meets regulations as they are applicable to wholesalers. Other registered entities in the supply chain have their own independent responsibility to achieve compliance.

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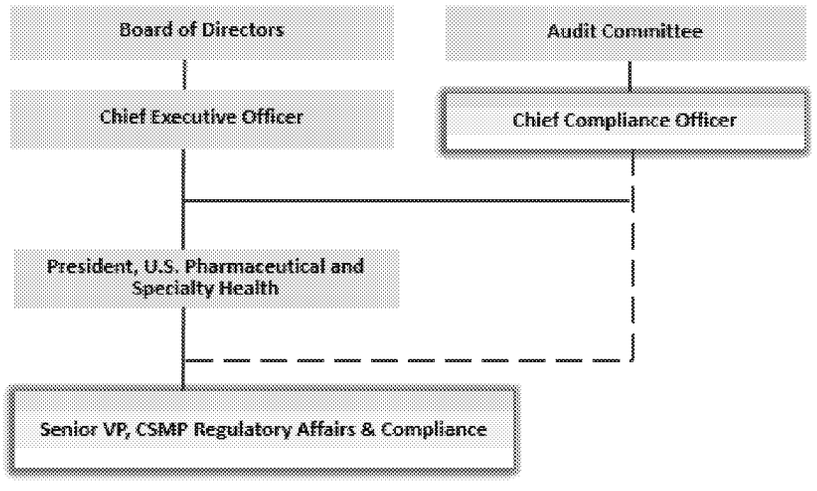
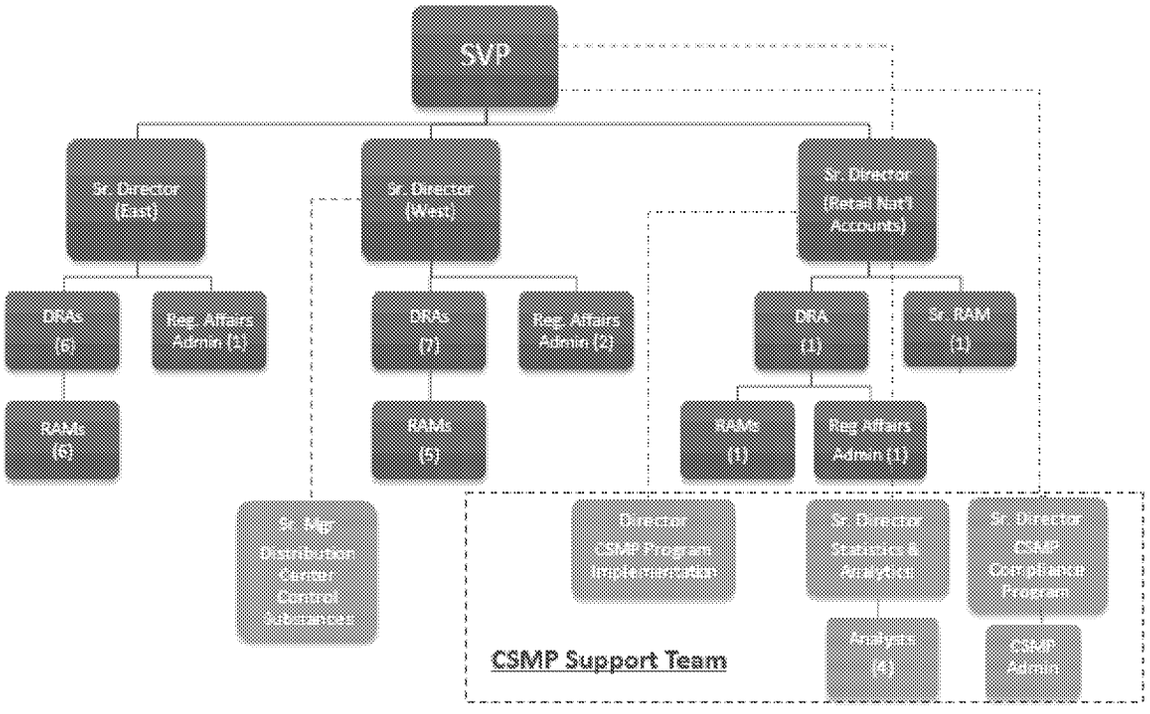
3. Governance

Corporate Overview



CSMP, Regulatory Affairs & Compliance Organization



CSMP Regulatory Affairs & Compliance Organization – Roles and Responsibilities

- Senior Vice President, CSMP Regulatory Affairs and Compliance (SVP):
  - Oversees CSMP development and team
  - Develops CSMP strategy for U.S. Pharma
  - Represents CSMP to the enterprise and to external parties

- Senior Director, CSMP Regulatory Affairs (SrDRA):
  - Manages and understands the CSMP profile of Retail National Account Customers and national trends (i.e. top purchasers, customer base, and diversion trends)
  - Makes specific Customer decisions within SrDRA authority

- Director, CSMP Regulatory Affairs (DRA):
  - Manages and understands CSMP profile of Retail National Account Customers and national trends (i.e. top purchasers, customer base, and diversion trends)
  - Conducts Customer Due Diligence (see Section 4) at the direction of SrDRAs
  - Makes specific Customer decisions within DRA authority

- Regulatory Affairs Manager, CSMP Regulatory Affairs (RAM):
  - Conducts Customer Due Diligence (see Section 4) at the direction of DRAs or SrDRAs
  - Understands the CSMP profile of specific RNA Customers, and relevant geographic diversion trends

- Regulatory Affairs Administrator, CSMP Regulatory Affairs (RAA):
  - Conducts Due Diligence (see Section 4) support within the RAA authority
  - Provides administrative support for the CSMP, and acts as a primary point of administrative contact for Regulatory Affairs and RNA Support Solutions for onboarding and threshold change requests (TCRs)
    - RNA Support Solutions is a centralized business team that acts as a liaison for RNA Customers in a variety of areas, such as contract administration/compliance, accounts receivable, generic formulary management, and new Customer transitions.

CSMP Regulatory Operating Committee

- The Regulatory Operating Committee (ROC) meets periodically and has overall responsibility for:
  - Program-based decisions regarding the CSMP
  - Implementation and execution of CSMP enhancements
  - Hiring and onboarding of the Regulatory Affairs team
  - Supporting the technology and work needs of the Regulatory Affairs team

- ROC members include:
  - SVP, CSMP Regulatory Affairs and Compliance
  - SrDRA, CSMP Regulatory Affairs & Compliance – East Region
  - SrDRA, CSMP Regulatory Affairs & Compliance – West Region
  - SrDRA, CSMP Regulatory Affairs & Compliance – Retail National Accounts
  - SrDRA, CSMP Regulatory Affairs & Compliance – Statistics and Analytics
  - Sr. Counsel, Distribution Operations & Regulatory Affairs

- Representatives of the supporting functions (e.g. Sr. Director, Compliance & Ethics, CSMP Regulatory Affairs & Compliance), other McKesson businesses (e.g. Director, Regulatory Affairs, McKesson Specialty Health), and outside legal counsel participate in ROC meetings and provide support and oversight as determined by the ROC.

Controlled Substance Compliance Program National Governance Committee

- The Controlled Substance Compliance Program National Governance Committee ("Committee") meets periodically and has high-level oversight of:
  - U.S. Pharma's compliance with the CSMP
  - U.S. Pharma's compliance with the Controlled Substances Act ("CSA") and its implementing regulations

- Committee members include:
  - President, U.S. Pharmaceutical and Specialty Health (Chair)
  - SVP, Regulatory Affairs and Compliance, U.S. Pharmaceutical and Specialty Health
  - SVP, Distribution Operations
  - SVP and Chief Operating Officer
  - SVP, Retail National Accounts
  - SVP, Chief Financial Officer, U.S. Pharmaceutical and Specialty Health
  - SVP, Human Resources, U.S. Pharmaceutical and Specialty Health
  - President, McKesson Specialty Provider Organization
  - Representative(s) from the Law Department
  - Representative(s) from Internal Audit
  - At the discretion of the Committee, other individuals may participate in Committee meetings and provide support and oversight as determined by the Committee.

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4. Due Diligence Overview

Due Diligence is the process by which the RNA Regulatory Affairs team gathers information from a variety of internal and external sources to advise CSMP decisions concerning RNA Chain/Customers, or to enhance its knowledge of RNA Chains/Customers. Such information may be derived from (but not limited to) the following sources:

- Purchase reports and analytics
- Customer dispensing data
- Customer/Chain questionnaires (if applicable)
- Chain policies and procedures related to controlled substances
- State and federal licensing/registration authorities
- Customer interactions, e.g. telephone calls, Chain headquarters ("HQ") site visits, pharmacy site visits
- Open source research

Due Diligence is performed during the following scenarios, each of which has its own specific SOP outlined in this Manual:

- Onboarding – See Section 11
- Threshold Change Requests ("TCRs") – See Section 12
- RNA Chain Threshold Reviews – See Section 13
- Proactive RNA Customer Reviews – See Section 14
- External Event-triggered RNA Customer Reviews – See Section 15

Note: Due Diligence reviews are viewed and conducted in the context of RNA Chain- and/or RNA segment-level norms and trends. The RNA Regulatory Affairs team may also reference the Red Flags outlined in the ISMC Operating Manual when conducting site visits/registrant-level investigations.

- Red Flags are statistical and non-statistical indicators or areas of possible concern regarding a Customer's controlled substance ordering/dispensing, disciplinary history, compliance procedures, or other aspect(s) of its business. Red Flags are not necessarily indicative of diversion, as the facts and circumstances are often case specific and the various aspects of a Customer's business model may provide an explanation or justification surrounding any possible Red Flags.

4.1 Managerial Oversight – As specified throughout this Manual, RAMs will escalate any unresolved Red Flags identified during any Due Diligence procedure to the DRA for review and consultation. If the Red Flag(s) remain unresolved, the DRA will escalate the matter to the SrDRA for final resolution. Overall, RNA Regulatory Affairs team members will escalate Red Flags to their direct supervisor, i.e. RAM to DRA, DRA to SrDRA.

4.2 More Commonly Abused Drugs – McKesson designates certain controlled substances as "more commonly abused drugs" and thus subject to additional monitoring. The list below may be updated by the ROC periodically:

1. Oxycodone
2. Hydrocodone
3. Hydromorphone
4. Methadone
5. Morphine
6. Carisoprodol
7. Alprazolam
8. Tramadol
9. Oxymorphone

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5. RNA Chain Compliance Programs

Most RNA Chains have internal and centralized compliance/oversight related to controlled substances. RNA Regulatory Affairs leverages the information sources listed in Section 4 above to better understand each RNA Chain's program to support CSMP decision-making and complement CSMP procedures.

The Due Diligence procedures used by the RNA Regulatory Affairs team generally align with those outlined in the ISMC Controlled Substance Monitoring Program Operating Manual, subject to some differences due to unique RNA Customer segment characteristics.

There is a small subset of Customers within the RNA segment that does not have internal and centralized compliance/oversight related to controlled substances. Customers within this subset profile and operate like independent pharmacies. Such Customers that are affiliated with a RNA Chain in some way, but do not have corporate governance/oversight of controlled substance-related processes or practices will be reviewed using relevant due diligence procedures as outlined in the ISMC Operating Manual.

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6. Roles and Responsibilities Overview

Specific roles and responsibilities may vary depending on the Due Diligence procedure (outlined below as applicable), but the following is a general outline of roles and responsibilities related to RNA Customer Due Diligence:

- **Customer (RNA Chain HQ Contact)** is responsible for initiating Chain-wide/Customer-specific onboarding requests and TCRs, and providing responses to questions and data requests from McKesson to support such requests and other Due Diligence reviews, if applicable.

- **RNA Support Solutions** is typically responsible for initial interactions with the RNA Customer, and gathering necessary information and documentation for onboarding/TCR submissions and other Due Diligence reviews, if applicable.

- **SrDRA** is responsible for ensuring Due Diligence procedures are followed by his/her team, and manages these procedures in the event one is escalated to him/her. The SrDRA determines Due Diligence decisions within the SrDRA's decision-making authority, and communicates with RNA Support Solutions as needed.

- **DRA** is responsible for managing Due Diligence procedures for Customers within the RNA segment. Additionally, the DRA ensures each RNA Customer submission is accompanied by proper documentation, and appropriate Due Diligence is conducted based on the request and any areas of concern. The DRA determines Due Diligence decisions within the DRA's decision-making authority, and communicates with RNA Support Solutions as needed.

- **RAM** is also responsible for managing Due Diligence procedures for Customers within the RNA segment. Additionally, the RAM ensures each RNA Customer submission is accompanied by proper documentation, and appropriate Due Diligence is conducted based on the request and any areas of concern. The RAM determines Due Diligence decisions within the RAM's decision-making authority, and communicates with RNA Support Solutions as needed.

- **RAA** is responsible for communicating with RNA Support Solutions, conducting Due Diligence as assigned, compiling/managing documentation supporting the Due Diligence decision, and filing documentation as required in the relevant SOP.

Note: McKesson's communication with the Customer may be done by RNA Support Solutions and/or RNA Regulatory Affairs as appropriate.

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7. Communication Overview

The RNA Regulatory Affairs team uses a centralized mailbox (RNARegulatorySubmissions) for most communication with internal RNA partners. Although individual members of the RNA Regulatory Affairs team may reach out personally to internal and external RNA partners as needed, decisions and/or requests for information regarding Due Diligence procedures are typically filtered through RNA Support Solutions to RNA Chains. Procedure-specific communication is outlined below as applicable.

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8. Documentation Overview

Different Due Diligence procedures may require unique documentation, but the steps below are typically applied to all Due Diligence documentation:

- Once a decision is made, the completed Investigative Report (dated as of the date it was finalized) and/or TCR Form (as applicable, and dated as of the date it was finalized) will be

converted to Portable Document Format ("PDF") and uploaded to the appropriate RNA Chain/Customer Due Diligence folder in the R:Drive.

- An Investigative Report ("IR") is a report template used by Regulatory Affairs personnel to document information gathered from internal and external sources during a Due Diligence review, and to record the outcome/findings of the review.
- A TCR Form is a standard template used to capture relevant information related to a threshold change request from a RNA Customer, and is typically used in place of an Investigative Report for TCRs.

- Documentation is to be completed and placed in the RNA Chain/Customer Due Diligence folder by the RNA Regulatory Affairs team within 45 business days of the completion date as defined for each Due Diligence procedure below:
  - Onboarding – Date the family code is entered in SAP (see Section 9)
  - Threshold Change Requests (TCRs) – Date the threshold(s) change is made in SAP, or the date of denial or cancelation, if applicable
  - RNA Chain Threshold Reviews – Date the threshold changes are made in SAP
  - Proactive RNA Customer Reviews – Date the RNA Regulatory Affairs team member completed the proactive review
  - External Event-triggered RNA Customer Reviews – Date the RNA Regulatory Affairs team member completed the event-triggered review

- The Due Diligence folder may contain, as applicable:
  - Investigative Report(s)
  - TCR Form
  - Chain Questionnaire – A standard document that contains questions regarding items such as the RNA Chain's business model, controlled substance compliance oversight, and controlled substance sourcing that is intended to be filled out by the RNA Chain's HQ team.
  - Dispensing data and any associated analytics
  - Purchase history, threshold change history, and/or omit data
  - RNA Regulatory Affairs may elect to include additional supporting documentation in the Due Diligence folder to the extent relevant. Such documentation may include:
    - Copies of any disciplinary actions by a state board of pharmacy or controlled substance authority against the RNA Chain/Customer or relevant personnel;
    - Copies of adverse media articles regarding the RNA Chain/Customer or relevant personnel;
    - Any additional information received from the RNA Customer.

- Once all final documents have been converted to PDF format and placed in the RNA Chain/Customer Due Diligence folder in the R:Drive, all draft documents are to be deleted. **Note:** Financial, patient identifiable or other personal health information should not be included as part of any CSMP process. Should such information be received, please consult with the Law Department.
- The RAA will update the RNA Tracker (see Appendix D) to reflect the Due Diligence procedure that was completed.

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9. Threshold Procedures and SAP Data Entry

The CSMP monitors orders for controlled substances through the use of monthly thresholds. RNA Customers eligible to purchase controlled substances have a monthly threshold assigned to each controlled substance base code within their assigned family code. The monthly threshold caps the total amount of doses that a RNA Customer may purchase for a controlled substance base code in any particular calendar month.

The following processes are to be followed to establish thresholds:

- **Onboarding Thresholds** – Monthly controlled substance base code thresholds are set at the completion of a RNA Customer onboarding, which establishes that Customer's eligibility to purchase controlled substances from McKesson. If the RNA Customer is a new, start-up pharmacy with no dispensing history, the Customer will be assigned the standard default thresholds for RNA as set forth for the RNA1 family code in SAP. For a RNA Customer that is not a start-up pharmacy, thresholds may be either family defaults or Customer-specific thresholds established based on the Customer's recent dispensing history as determined based on the dispensing data provided, and the overall Due Diligence evaluation of the Customer as part of the onboarding procedure (see Section 11).
  - Family Defaults (Default Onboarding) – The RNA1 family code is used to designate those Customers that fall within the RNA Customer Segment; however, each RNA1 family base code default threshold is the same as the AA00 family base code default threshold used by the ISMC Customer Segment for retail customers.
  - Customer-specific Thresholds (Custom Onboarding) – If RNA1 family default thresholds for one or more base codes cannot accommodate recent dispensing (based on dispensing data provided by the prospective Customer), customized thresholds for such base codes may be established to more accurately reflect dispensing levels.

- **Non-Onboarding Thresholds** (i.e. types of threshold-setting processes that take place subsequent to RNA Customer onboarding):
  - TCRs and Temporary TCRs (see Section 12)
  - Due Diligence Adjustments – Threshold adjustments made to one or more base codes not listed on a TCR Form, or threshold adjustments made in connection with a documented Due Diligence review of a RNA Chain/Customer.
    - Appropriate documentation, as specified in the relevant SOP, must be included in the Customer's file in the R:Drive.
    - If the Due Diligence Adjustment is an increase to the Customer's threshold(s), Sr. DRA approval is required and must be included in the required documentation saved in the Customer's file in the R:Drive.
  - Programmatic Adjustments – Threshold adjustments initiated by the Regulatory Affairs Department that are approved in advance by the ROC. These changes will be made in an automated fashion and will not be separately documented in Due Diligence reviews that are maintained in Chain/Customer files. However, they will be documented in the CSMP Program Log (see Sub-Section 16.1).

Standard reason texts are to be applied when onboarding and/or changing RNA Customer thresholds in SAP. The reason text will vary depending on the Due Diligence procedure. The Threshold Text Builder tool (link) can be used to automatically create the "Reason for Change" field associated with the SAP entry. The SAP update shall include the following conventions in the text field:

- Notate the relevant scenario:
  - Default Onboarding
  - Custom Onboarding
  - TCR
  - TCR Temp
  - Due Diligence Adjustment
  - Programmatic Adjustment
  - **Note:** Instances may arise in which a unique reason text is applied to a RNA-specific scenario. For example, see Sub-Section 13.5.
- Three letter initials of the RNA Regulatory Affairs team member making the change
- Date of approval
- Example entries:

Reason for Change	SAP Entry Requirements	SAP Entry Example: "Reason for Change" Field
Default Onboarding	Default Onboarding-RA Three Letter Initials-Date of Approval	Default Onboarding-JMD-092815

Reason for Change	SAP Entry Requirements	SAP Entry Example: "Reason for Change" Field
Custom Onboarding	Custom Onboarding-RA Three Letter Initials-Date of Approval	Custom Onboarding-JMD-092815
TCR	TCR-Previous Threshold-RA Three Letter Initials-Date of Approval	TCR-From 3500-JMD-092815
Temporary TCR	TCR Temp-Previous Threshold-RA Three Letter Initials-Date of Approval	TCR Temp-From 3500-JMD-092815
Due Diligence Adjustment	DD Adjustment-Previous Threshold-RA Three Letter Initials-Date of Approval	DD Adjustment-From 3500-JMD-092815
Programmatic Adjustment	Programmatic Adjustment-RA Three Letter Initials-Date of ROC Approval	Programmatic Adjustment-JMD-092815

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10. Suspicious Order Monitoring and Reporting

- **Suspicious Order Monitoring System** – The CSMP monitors orders for controlled substances through the use of monthly thresholds. Customers eligible to purchase controlled substances have a monthly threshold assigned to each controlled substance base code which they are eligible to purchase. The monthly threshold caps the total amount of doses that a customer may purchase for a controlled substance base code in any particular calendar month. If a customer's order line makes its cumulative monthly total exceed the established threshold, the customer's order line is blocked and not filled. These orders are flagged as "V" Code Omits.

- **Reporting Suspicious Orders** – Orders with a "V" Code Omit are compiled in a Suspicious Order Report which is generated at the end of each business day. The report is automatically transmitted to DEA Headquarters at the end of each business day through DEA's website. The reports are submitted in the same format as ARCOS data. Suspicious orders are reported by NDC number. The customer shall be notified that the order has been purged from the system and will not be filled.

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11. Onboarding Procedure

Note: For those prospective Customers that operate and profile like independent retail pharmacies, refer to the ISMC Operating Manual for onboarding procedures. SrDRA must grant final approval for all independent-like customer onboardings.

- **Purpose** – This SOP defines the required processes for onboarding RNA Customers, which includes both entire Chains and individual registrants within a Chain. This SOP is to be applied to (1) an existing RNA Customer that desires to purchase controlled substances for the first time from McKesson, or (2) a prospective RNA Customer, and includes, for purposes of this SOP, any RNA Customer that may have been a McKesson customer in the past, but is now requesting to again purchase controlled substances from McKesson ("prospective RNA Customer" or "prospective RNA Chain"). Any decisions resulting from this procedure are limited to controlled substances and do not preclude a RNA Customer's eligibility to purchase non-controlled substance products from McKesson.

- **Scope** – This SOP includes participation from prospective RNA Chains/Customers, RNA Support Solutions, RNA Executives, and RNA Regulatory Affairs. Proper execution of the procedure results in new RNA Customers that have been appropriately reviewed and documented by RNA Regulatory Affairs, prior to granting eligibility to purchase controlled substances. **Note:** RNA Executives are senior business leaders who manage and are the primary owners of relationships with multiple RNA Chain accounts.

RNA Chain Onboardings

11.1 Submitting an Onboarding Request for a RNA Chain – RNA Support Solutions/Executives are the primary points of contact for a prospective RNA Chain. The following is required for a RNA Regulatory Affairs review and approval of a prospective RNA Chain:
- Three (3) months of dispensing data for all individual registrants in the Chain;
- DEA registrations and state board(s) license(s)/registration(s) for all registrants within the Chain shall be obtained and confirmed through the existing RNA Support Solutions processes.
- The dispensing data and any other accompanying documentation shall be submitted to Regulatory Affairs.

11.2 Initial Processing of a RNA Chain Onboarding Request – Upon notification of a RNA Chain onboarding request, RNA Regulatory Affairs shall:
- Determine if the RNA Chain has previously been a McKesson customer.
- Set up a new Chain folder in the R:Drive.

- Save all documentation received to the Chain folder in the R:Drive; individual Customer folders within the Chain may be set up as needed.
- All onboarding requests for new RNA Chains should be escalated to the SrDRA, who is responsible for conducting and/or delegating Due Diligence activities and must grant final approval for all RNA Chain onboardings.

11.3 Due Diligence for a RNA Chain Onboarding – Due Diligence must be conducted for every RNA Chain onboarding request. The level of diligence will vary depending on each request, but the SrDRA (with assistance from other Regulatory Affairs team members as needed) shall ensure the following items and activities are completed:

- Review dispensing data to identify any Chain-level or registrant-specific Red Flags. Any findings shall be reviewed with the prospective Chain's HQ team, and further escalation may be conducted as needed.
- Conduct a telephone call(s) or HQ site visit to learn about the prospective Chain's corporate structure, compliance program/structure, corresponding responsibility best practices, data monitoring capabilities, business model, and overall diligence efforts.
- Obtain images/photos of HQ and examples of store formats.
- Check the OIG Exclusion Database (https://exclusions.oig.hhs.gov) for the prospective Chain and relevant personnel.
- Conduct an internet search for additional background information on the Chain.
- Obtain and review a completed Chain Questionnaire; follow-up as needed.
- Document the Due Diligence in an Investigative Report.

11.4 Decision Process for a RNA Chain Onboarding – In consultation with RNA Regulatory Affairs leadership and RNA Executives, only SrDRAs may approve/deny onboarding new RNA Chains. SrDRAs are responsible for logging any denials for onboarding RNA Chains into the CSMP Actions Tracking Tool.

11.5 Documentation for a RNA Chain Onboarding – See Section 8. Rather than completing an Investigative Report for each individual Customer within the Chain, a Chain-level Investigative Report will be documented in the RNA Chain's R:Drive folder. In addition, all information referenced in Sub-Section 11.3 will be included in the RNA Chain's R:Drive folder.

11.6 Threshold Establishment and Data Entry for a RNA Chain Onboarding – See Section 9. Default Onboarding or Custom Onboarding thresholds will be loaded as appropriate.

11.7 Communication Relating to a RNA Chain Onboarding – See Section 7.

Individual Registrant Onboardings Within a RNA Chain

11.8 Submitting an Onboarding Request for an Individual Registrant – RNA Support Solutions personnel are the primary point of contact for a prospective RNA Customer (individual registrant). The following is required for a RNA Regulatory Affairs review and approval of a prospective RNA Customer:

- Three (3) months of dispensing data unless the pharmacy is a start-up pharmacy with no dispensing history, or the prospective Customer has been in business for less than three (3) months;
- Images of the prospective Customer's DEA registration and state board(s) license(s)/registration(s).
- The dispensing data, registration/license(s), and any other accompanying documentation shall be submitted to RNA Regulatory Affairs.

11.9 Initial Processing of an Onboarding Request for an Individual Registrant – The RAA/RAM shall monitor the RNARegulatorySubmissions mailbox for new onboarding requests, and upon receipt of a submission shall:

- Record the request in the RNA Tracker.
- Review the CSMP Actions Tracking Tool for any prior action, if applicable.
- Set up a Customer folder in the R:Drive under the appropriate Chain; the following name convention should be used: <Pharmacy Name_9-digit DEA Registration Number>
- Save all documentation received to the Customer's R:Drive folder.
- Initiate a Due Diligence review.

11.10 Due Diligence for an Individual Registrant Onboarding – Due Diligence must be conducted for every onboarding request. The level of diligence will vary depending on each request, but the RAM/DRA (with assistance from the RAA as needed) shall ensure the following items and activities are completed:

- Determine whether the prospective Customer's physical location matches the address listed on its DEA registration. (The SrDRA may direct a member of the Regulatory Affairs Department to conduct a site visit as needed.)
- Include an image of the pharmacy's exterior; actual photos are not required, and images obtained via an open source internet search are acceptable. **Note:** Images are not required if the business is a start-up pharmacy under construction.
- Conduct a DEA registration review and verification for the pharmacy. Also note if there are any limitations or restrictions for specific schedules on the DEA registration.
- Check state licenses for the pharmacy and pharmacy personnel (if applicable) through the state board of pharmacy website, and where applicable, check the state controlled

substance authority website to ensure that all licensure is current and free of any relevant disciplinary information.

- Check the OIG Exclusion Database (https://exclusions.oig.hhs.gov) for the pharmacy and pharmacy personnel (if applicable).
- Conduct an internet search on the pharmacy and pharmacy personnel (if applicable) for any relevant information.
- Review the prospective Customer's dispensing data (if applicable), or any relevant internal data.
- Document the Due Diligence in an Investigative Report.

11.11 Decision Process for an Individual Registrant Onboarding

- RAMs may approve a RNA Customer onboarding provided no Red Flags are identified and unresolved; otherwise the DRA must review.
- DRA may approve a RNA Customer onboarding provided no unresolved Red Flags are identified; otherwise SrDRA must review.

11.12 Documentation for an Individual Registrant Onboarding – See Section 8. SrDRAs are responsible for logging any denials for onboarding into the CSMP Actions Tracking Tool.
Note: At times, an existing Chain Customer may acquire, purchase files from, or merge with a group of pharmacies or another chain. In such cases, a single Investigative Report may be used to document Due Diligence reviews for multiple pharmacies rather than individual reports for each pharmacy.

11.13 Threshold Establishment and Data Entry for an Individual Registrant Onboarding – See Section 9. Default Onboarding or Custom Onboarding thresholds will be loaded as appropriate.

- *Sister Stores* – RNA Chains may provide a "sister store" to establish custom thresholds for a start-up pharmacy. Sister stores are existing pharmacies within the same RNA Chain that profiles similarly to the new pharmacy based on factors such as volume, demographics, and geography. Per common industry practice, the RNA Regulatory Affairs team may use the sister store's purchasing history data to customize select base codes.

11.14 Communication Relating to an Individual Registrant Onboarding – See Section 7.

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12. Threshold Change Request (TCR) Procedure

Note: For those RNA Customers that operate and profile like independent retail pharmacies, refer to the ISMC Operating Manual for TCR procedures.

- **Purpose** – This SOP defines the required processes for conducting RNA Customer TCR reviews. This TCR SOP is to be applied to RNA Customer requests to increase thresholds for controlled substance purchases. This SOP is not intended to cover Due Diligence Adjustments or Programmatic Adjustments.

- **Scope** – This SOP involves the participation of RNA Chains/Customers, RNA Support Solutions, and RNA Regulatory Affairs. Proper execution of the TCR procedure results in threshold decisions that are appropriately reviewed and documented by RNA Regulatory Affairs. Not all TCRs will result in a modification to a RNA Customer's threshold(s).

12.1 Submitting a TCR – TCRs are triggered by a RNA Customer's desire to increase the threshold for a particular controlled substance base code(s). All TCRs must be reviewed by the appropriate RNA Chain HQ team prior to submission to McKesson. The RNA Regulatory Affairs team will not accept any TCRs directly from an individual pharmacy. RNA Support Solutions personnel are the primary point of contact for the RNA Chain/Customer when initiating the TCR procedure, but RNA Regulatory Affairs may follow up with the RNA Chain/Customer directly to gather additional information as needed.

- RNA Support Solutions shall complete the "RNA Support Solutions" portion of the TCR Form. In addition, RNA Support Solutions is required to collect the following supporting information from the Customer:
  - A minimum of three (3) months of dispensing for all permanent TCRs unless the business has been in operation for less than three (3) months.
  - RNA Customer-provided detailed rationale for the request should be recorded on the first page of the TCR Form. If the rationale is provided in a separate letter, email, etc. refer to this document in the TCR Form.
  - Completed TCR Form and accompanying documentation should be submitted by RNA Support Solutions via email to the RNARegulatorySubmissions mailbox.

- *Temporary TCRs* – Temporary threshold changes may be granted in the case of inventory needs due to a natural disaster, theft/loss, recalls or return of expired products.
  - Dispensing data is not required for a temporary TCR.
  - RNA Customer must provide satisfactory documentation supporting the request, which in the case of a theft/loss includes a copy of the DEA Form 106 or a police

report. For a temporary TCR due to theft/loss, threshold increases will be limited to the base codes and quantities identified in the DEA 106 or police report.

- RAM/DRA shall ensure that all relevant documentation and the TCR Form are filed in the Customer's R:Drive folder.
- When granting a temporary TCR, the change(s) should be submitted in the system as a "temporary increase." This assures that the threshold will automatically revert to the original threshold at the beginning of the subsequent month.

12.2 Initial Processing of a TCR – The RAA/RAM shall monitor the RNARegulatorySubmissions mailbox for new TCRs, and upon receipt of a submission shall:

- Record the TCR in the RNA Tracker.
- Review the TCR submission for completeness, and notify the submitter of any missing items, such as dispensing data or a business justification, as applicable.
- If a folder for the RNA Customer does not already exist, set up a folder in the R:Drive under the appropriate Chain for the Customer using the following naming convention: <Pharmacy Name_9-digit DEA Registration Number>.
- Save all documentation received to the Customer's R:Drive folder.
- **Note:** All TCRs are typically initially routed to a RAM, but DRA/SrDRA may also conduct Due Diligence reviews as needed.

12.3 Due Diligence for a TCR – Due Diligence must be conducted for every TCR. The level of diligence will vary depending on each request, but the RAM/DRA (with assistance from the RAA as needed) shall ensure the following items and activities are completed:

- Review the reason for the TCR and complete the portion of the TCR Form assigned to RNA Regulatory Affairs (including input of the current Customer thresholds from SAP).
- Review relevant data, i.e. dispensing or usage.
- Review the pharmacy's purchase history and threshold adjustment history for the requested base codes using the Solver and BW when necessary.
- Save supporting data reviewed in the Customer folder.
- Conduct a Customer call, site visit, or other communication as needed. Such supporting Due Diligence should be documented on the TCR Form and/or in an Investigative Report.
- If unresolved Red Flags are identified, escalate to the DRA/SrDRA, in accordance with Sub-Section 12.4; annotate the escalation on the TCR Form.

12.4 Decision Process for a TCR

- RAMs may approve a TCR (temporary or permanent) provided no Red Flags are identified and unresolved; otherwise, the DRA must review and approve.

- DRAs may approve a TCR (temporary or permanent) provided no Red Flags are identified and unresolved; otherwise, the SrDRA must review and approve.
- If a TCR is escalated by the RAM to the DRA, or by the DRA to the SrDRA, the escalation should be noted on the TCR Form or in the Investigative Report (if applicable). The DRA/SrDRA shall complete the following diligence:
  - Review Red Flags identified by the RAM/DRA.
  - Review all documentation and discuss with the RAM/DRA and/or RNA Customer. In the event of Red Flag escalation to the SrDRA, the SrDRA will make the final decision.
- In the event a RNA Customer requests an adjustment to one or more thresholds based upon a time-sensitive and unforeseen circumstance not contemplated in this Manual, the SrDRA will have discretion in making such an adjustment based upon the justification and need.

  The RNA Customer-provided rationale for such a request should be recorded on the first page of the TCR Form. If the rationale is provided in a separate letter, email, or other document, refer to this document in the TCR Form. However, because of the time sensitivity of these types of requests, the SrDRA may, at his/her discretion, determine that dispensing data is not required. Any increases made to the RNA Customer's threshold(s) under this provision will not be permanent and will be limited to the base code(s) and quantities being impacted by the unforeseen circumstance. In such instances, the SrDRA shall complete the following activities:
  - Review the Customer's purchase history and current threshold(s) to determine whether there is a need to adjust any thresholds in whole or in part to address the unforeseen circumstance.
  - Validate that the Customer's DEA registration is current and without limitations for purchasing the base code(s) requested.
  - Document any adjustment and base codes that were increased on the second page of the TCR Form or in the Investigative Report (if applicable). The documentation will be placed in the Customer's Due Diligence file on the R:Drive.

12.5 Documentation for a TCR – See Section 8. Based on the Due Diligence and level of authority, the RAM/DRA or SrDRA shall decide to approve, approve with modifications, deny, or cancel a TCR. The decision is to be documented on the TCR Form or in the Investigative Report, if applicable.

12.6 Communication Relating to a TCR – See Section 7.

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13. RNA Chain Threshold Review Procedure

- **Purpose** – This SOP defines the required processes for RNA Chain threshold reviews. This SOP is to be applied to: 1) RNA Chain requests to increase or decrease thresholds for one or more base codes across multiple Customers within the Chain (typically due to a controlled substance sourcing change); and 2) RNA Regulatory Affairs-initiated base code threshold reductions among a group of RNA Customers and/or all Customers within a Chain or across multiple Chains.

- **Scope** – This SOP involves the participation of RNA Chains/Customers (if applicable), RNA Support Solutions (if applicable), and RNA Regulatory Affairs. Proper execution of the procedure results in threshold changes that are appropriately reviewed and documented by RNA Regulatory Affairs. Not all Chain threshold reviews will result in threshold changes of the reviewed base code(s) for all RNA Customers within a RNA Chain.

Customer-initiated RNA Chain Threshold Reviews

Note: Example of a Customer-initiated business model change scenario – A Chain previously sourced Schedule II controlled substances through its own warehouse, but is transitioning sourcing of base code(s) within that drug schedule to McKesson.

13.1 Submitting a Customer-initiated RNA Chain Threshold Review – RNA Support Solutions personnel are the primary point of contact for the RNA Chain when initiating the Chain threshold review procedure, but RNA Regulatory Affairs may follow up with the RNA Chain directly to gather additional information as needed. **Note:** Although RNA Chains often initiate this procedure, there are instances in which a RNA Chain does not formally request a review, yet RNA Regulatory Affairs identifies a business model change through purchase or omit data reviews. Such instances would also prompt a RNA Chain threshold review by RNA Regulatory Affairs (see Regulatory-initiated Chain Threshold Reviews).

- A TCR Form or Investigative Report should be used for Chain threshold reviews that include a request to increase thresholds. If applicable, RNA Support Solutions shall complete the "RNA Support Solutions" portion of the TCR Form. In addition, RNA Support Solutions is required to collect the following supporting information from the Chain:
  - A minimum of three (3) months of dispensing for all individual Customers included in the request.
  - Customer-provided detailed rationale for the request should be recorded on the first page of the TCR Form, if applicable. If the rationale is provided in a separate letter, email, etc. refer to this document in the TCR Form.

- **Note:** A completed TCR Form and accompanying documentation should be submitted by RNA Support Solutions via email to the RNARegulatorySubmissions mailbox.

13.2 Initial Processing of a Customer-initiated RNA Chain Threshold Review – The RAA/RAM shall monitor the RNARegulatorySubmissions mailbox for new RNA Chain threshold review requests, and upon receipt of a submission shall:

- Record the request in the RNA Tracker.
- Review the request submission for completeness, and notify the submitter of any missing items, such as dispensing data or a business justification, as applicable.
- Save all documentation received to the RNA Chain's R:Drive folder.
- **Note:** While Customer-initiated Chain threshold reviews are typically initially routed to a RAM, the DRA/SrDRA may also conduct Due Diligence reviews as needed.

13.3 Due Diligence for a Customer-initiated RNA Chain Threshold Review – Due Diligence must be conducted for every RNA Chain threshold review. The level of diligence will vary depending on each request, but the RAM/DRA (with assistance from the RAA as needed) shall ensure the following items and activities are completed:

- Review the reason for the request and complete the portion of the TCR Form assigned to RNA Regulatory Affairs, if applicable.
- Review dispensing data. **Note:** Dispensing data will be used to create new thresholds. Depending on the scenario, the specific logic used to generate new thresholds may vary.
- Review the pharmacies' purchase history for the requested base codes.
- Save supporting data reviewed in the Chain folder.
- Conduct a Customer call, site visit, or other communication as needed. Such supporting Due Diligence should be documented on the TCR Form and/or in an Investigative Report.

13.4 Decision Process for a Customer-initiated RNA Chain Threshold Review – Although members of the RNA Regulatory Affairs team may conduct the initial processing and Due Diligence for a RNA Chain threshold review, the SrDRA must grant final approval for any Customer-initiated Chain threshold changes.

13.5 Base Code Maximums from a RNA Chain – A RNA Chain may want to implement internally-created threshold maximums that are less than the thresholds used by McKesson. In such a case, a review would be conducted to ensure the RNA Customers' thresholds do not exceed Chain-generated maximums; however, RNA Regulatory Affairs will not increase existing thresholds to match Chain-generated maximums. Chain-generated maximums are only used

if they are lower than the McKesson-generated thresholds. As noted above in Section 9, this type of threshold adjustment may warrant a unique reason text for this RNA-specific scenario.

13.6 Documentation for a Customer-initiated RNA Chain Threshold Review – See Section 8. A TCR Form/Investigative Report is not needed for each individual RNA Customer impacted by any Chain threshold changes, but a summary Investigative Report will be used to explain and document the reason for the review, the methodology used, and the scope of the changes. These Investigative Reports, along with any data (dispensing or purchases) and associated calculations should be saved in the Chain's R:Drive folder.

13.7 Communication Relating to a Customer-initiated RNA Chain Threshold Review – See Section 7.

RNA Regulatory Affairs-initiated Chain Threshold Reviews

Note: RNA Regulatory Affairs will conduct periodic proactive reviews of a RNA Chain's purchasing activity, and may reduce individual RNA Customers' thresholds as a result of such reviews. Such decreases may result from sourcing changes, as indicated by purchase data, or from natural declines in certain base codes over time. RNA Regulatory Affairs may or may not notify RNA Support Solutions and/or Chain HQ teams about such reductions. Only the SrDRA may approve Regulatory-initiated Chain Threshold Reviews.

13.8 Processing of a RNA Regulatory Affairs-initiated Chain Threshold Review – RNA Regulatory Affairs team members may review purchasing data, compare to existing thresholds, and apply logic to reduce gaps in partnership with the SrDRA as part of the RNA Regulatory Affairs-initiated Chain threshold review. Any reductions will be processed as Due Diligence Adjustments (see Section 9).

13.9 Documentation for a Regulatory-initiated Chain Threshold Review – See Section 8 and Sub-Section 13.6.

13.10 Communication for a Regulatory-initiated Chain Threshold Review – Per the Note above, RNA Regulatory Affairs may or may not notify RNA Chain HQ teams about this type of review, at the discretion of the SrDRA.

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14. Proactive RNA Customer Reviews

- **Purpose** – This SOP defines the required processes for proactive RNA Customer reviews, which are initiated by RNA Regulatory Affairs in an effort to "know our customer," both at the Chain and registrant level. Such reviews may be generated as a matter of routine and are not necessarily the result of one or more Red Flags being identified. Proactive reviews provide an added layer of monitoring within the CSMP to help identify potential areas of concern, and provide an opportunity to stay current with Chain-level and/or segment-wide controlled substance trends. **Note:** These reviews do not include those conducted in conjunction with a RNA Customer onboarding or TCR.

- **Scope** – This SOP involves participation from RNA Chains/Customers (if applicable), RNA Support Solutions (if applicable), and Regulatory Affairs. Proper execution of the procedure results in thorough RNA Customer reviews that are documented by RNA Regulatory Affairs. Such reviews may result in Due Diligence Adjustments and/or requests for additional information from RNA Customers, depending on the facts and circumstances of the review.

14.1 Initiation of a Proactive RNA Customer Review – The following items may prompt a "deeper dive" by RNA Regulatory Affairs into a particular RNA Chain/registrant's controlled substance activity and/or business model:

- *RNA Solver* – See Appendix B;
- *Chain Purchasing Data* – Reviewed by RNA Regulatory Affairs to identify high-level trends, as well as top purchasers of certain base codes;
- *Other Data Points* – Reviews of additional data, such as frequency of omits, may also identify areas that warrant further follow-up with a Chain;
- *Chain Interactions* – Scheduled communication/discussion with a RNA Chain, such as routine business reviews or speaking invitations, may prompt a review of that Chain's data even if no areas of concern were previously identified;
- *File Refresh* – RNA Regulatory Affairs may conduct a review in order to maintain up-to-date data on RNA Customers.

14.2 Due Diligence for a Proactive RNA Customer Review – The level of Due Diligence for proactive Customer reviews is based on the particular facts and circumstances as determined by RNA Regulatory Affairs personnel, and may include, but is not limited to, any of the following activities:

- Conduct a DEA registration review and verification for the pharmacy. Also note if there are any limitations or restrictions for specific schedules on the DEA registration.

- Check state licenses for the pharmacy and known pharmacy personnel (if applicable) through the state board of pharmacy website, and where applicable, check the state controlled substance authority website to ensure that all licensure is current and free of any relevant disciplinary information.
- Check the OIG Exclusion Database (https://exclusions.oig.hhs.gov) for the pharmacy and known pharmacy personnel (if applicable).
- Conduct an internet search on the pharmacy and known pharmacy personnel (if applicable) for any relevant information.
- Review any relevant internal data.
- Request dispensing data.
- Request an updated Customer Questionnaire, if applicable.
- Conduct a telephone/on-site discussion with Chain HQ personnel responsible for controlled substances processes and procedures.
- In coordination with Chain HQ personnel, conduct telephone interviews with pharmacy and/or district-level personnel with responsibility over the pharmacy of interest.
- Conduct an on-site pharmacy visit (may be done with assistance from ISMC RAM/DRA located in the market closest to the pharmacy).

14.3 Documentation for a Proactive RNA Customer Review – See Section 8. All proactive RNA Customer reviews should be documented in an Investigative Report, and filed in the appropriate RNA Chain or registrant folder on the R:Drive. If RNA Regulatory Affairs personnel deem any Due Diligence Adjustments are warranted based on the proactive RNA Customer review, such adjustments should be noted in the Investigative Report.

14.4 Communication Relating to a Proactive RNA Customer Review – RNA Regulatory Affairs will communicate with the RNA Chain depending on the level of Due Diligence conducted, but may not always provide notification that a proactive RNA Customer review has been done. RNA Support Solutions will be notified as needed.

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15. External Event-triggered RNA Customer Reviews

- **Purpose** – This SOP defines the required processes for external event-triggered RNA Customer reviews, which are prompted by a third party inquiry, information request, subpoena, or other incident relating to a third party. **Note:** These reviews do not include those conducted in conjunction with a RNA Customer onboarding or TCR.

- **Scope** – This SOP involves participation from RNA Chains/Customers (if applicable), RNA Support Solutions (if applicable), and Regulatory Affairs. Proper execution of the procedure results in thorough RNA Customer reviews that are documented by RNA Regulatory Affairs. Such reviews may result in Due Diligence Adjustments and/or requests for additional information from RNA Customers, depending on the facts and circumstances of the review.

15.1 Initiation of an External Event-triggered RNA Customer Review – The following events will prompt a Customer review by the RNA Regulatory Affairs team; external events not contemplated by this Manual may also trigger a Customer review.

- DEA Inquiry – A formal or informal inquiry from the DEA regarding a specific McKesson RNA Customer. **Note:** This does not include those situations in which DEA conducts a cyclic inspection of a distribution center and requests customer information, e.g., "Top 10" customers or the inquiry is otherwise inconsequential, e.g. verification of a customer's order(s), returns or related documentation.
- Other Government Inquiry – An inquiry by a government agency other than the DEA (e.g., state board of pharmacy, HHS, OIG, FBI, FDA) regarding a specific McKesson RNA Customer and related to controlled substances. **Note:** This does not include inquiries unrelated to controlled substances or an inquiry that is otherwise inconsequential, e.g. verification of a customer's order(s), return of product or related documentation.
- Supplier Notice/Inquiry – Written notice from a controlled substances supplier (e.g. Purdue Pharma, Mallinckrodt, Actavis) that the McKesson RNA Customer may present a controlled substance diversion concern.
- Known Adverse Media Event – Adverse events related to a McKesson RNA Customer that involve pharmaceuticals (e.g. law enforcement or regulatory action, controlled substance matters, and/or Medicare/Medicaid fraud), to the extent known to the Regulatory Affairs team.

15.2 Due Diligence for an External Event-triggered RNA Customer Review – See Sub-Section 14.2; the same Due Diligence activities may be conducted in this type of review.

15.3 Documentation for an External Event-triggered RNA Customer Review – See Section 8. All external event-triggered Customer reviews should be documented in an Investigative Report, and filed in the appropriate RNA Chain or registrant folder on the R:Drive. If RNA Regulatory Affairs personnel deem any Due Diligence Adjustments are warranted based on the external event-triggered RNA Customer review, such adjustments should be noted in the Investigative Report.

15.4 Communication Relating to an External Event-triggered RNA Customer Review – RNA Regulatory Affairs will communicate with the RNA Chain depending on the level of Due Diligence conducted, but typically does not provide details regarding an event-trigger. RNA Support Solutions will be notified as needed.

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16. Management Program Reporting

16.1 CSMP Program Log – CSMP changes, enhancements and events are tracked in the CSMP Program Log. Supporting documentation is stored in the Regulatory Affairs shared drive. The CSMP Program Log is housed in SharePoint with restricted access for viewing and data entry.

16.2 Customer CSMP Action Tracking

- Customers whose eligibility to buy controlled substances is terminated under the CSMP and prospective customers who are denied eligibility to buy controlled substances through the customer onboarding procedure are tracked by the SrDRA via the SharePoint CSMP Actions Tracking Tool located on the Regulatory Affairs SharePoint site.
- The CSMP Actions Tracking Tool is the system of record for these Regulatory Affairs decisions. Supporting documentation (e.g. diligence reports and other customer documentation) is stored in the R:Drive. The CSMP Actions Tracking Tool is housed in SharePoint with restricted access for viewing and data entry. Generated reports indicate the action taken by region, type (new or existing customer) and triggering event.

16.3 CSMP IT System Issue Reporting

- Purpose – Escalate all CSMP IT incidents that could originate from any internal or external source. All IT incidents must be reported as soon as possible to the CSMP IT System Reporting SharePoint site by the RNA Regulatory Affairs personnel experiencing the issue. The Analytics team will research the incident and escalate to the IT Help Desk as needed.
- How to report CSMP related IT system issues:
  - Go to the CSMP IT System Issue Reporting SharePoint site: http://pharma.mckesson.com/SiteDirectory/WMS/RegAffairs/Lists/CSMP%20IT%20System%20Issue%20Reporting/All%20Cases.aspx or by clicking here.
  - Click “Add new item” at the bottom of the SharePoint site.
  - Only enter values in the fields shown in the example to the right then click “Save”
  - Provide as much detail possible in “Issue Description” field (e.g., name of report/tool, which field(s) is experiencing problems, example of issue, etc.)
  - Attachments can be added if needed.

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17. Standard Training

17.1 Regulatory Affairs New Hire Training – All RNA Regulatory Affairs new hires shall be trained within the first 60 calendar days of employment. The manager of the new employee will provide training and oversight until he or she determines that the new hire has been adequately trained on corresponding CSMP responsibilities. Training shall include the following items:

- Review of CSMP Operating Manual.
- Instructor-led training sessions with an existing member of the Regulatory Affairs team.
- Instructor-led training sessions with a DRA or SrDRA concerning diversion trends and CSMP Red Flags of Diversion.
- Topics required per the 2017 Settlement Agreement with the DEA.

17.2 RNA Support Solutions Training – RNA Regulatory Affairs will leverage existing tools and training where applicable, and may also conduct additional training sessions with internal partners, particularly RNA Support Solutions, as needed.

17.3 Customer Education and Awareness – The Regulatory Affairs team conducts education and awareness efforts for our customers through formal training sessions, customer meetings, communications, and due diligence reviews.

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18. Record Retention

Records must be maintained in accordance with the McKesson's Record Retention Policy and Schedule (section ADM3014). The official record resides in the customer due diligence folder on the R:Drive. No copies for convenience, or drafts, etc. should be retained or deemed an official record.

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Appendix A – External Resources for Researching Diversion Trends, Prescription Drug Abuse, and Other Related Topics

- White House Office of National Drug Control Policy: http://www.whitehouse.gov/ondcp
- U.S. Drug Enforcement Administration: http://www.dea.gov/index.shtml and http://www.deadiversion.usdoj.gov/
- Centers for Disease Control and Prevention: http://www.cdc.gov/
- Substance Abuse and Mental Health Services Administration: http://www.samhsa.gov/
- National Institute on Drug Abuse: http://www.drugabuse.gov/
- U.S. Food and Drug Administration: http://www.fda.gov/
- National Association of Boards of Pharmacy: http://www.nabp.net/
- National Association of State Controlled Substance Authorities: http://www.nascsa.org/
- National Alliance for Model State Drug Laws: http://www.namsdl.org/
- Erowid: https://www.erowid.org/
- Healthcare Distribution Alliance (HDA): http://www.healthcaredistribution.org/ (Formerly HDMA)

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Appendix B – Analytical Tools

Note: The Regulatory Affairs Statistics & Analytics (RA S&A) Team owns the management and issuance of various CSMP analytical tools for use by Regulatory Affairs. CSMP analytical tools include the following:

- *RNA Solver*
  - Definition – Analytical tool that is refreshed monthly with the previous three months of purchase data. The RNA Solver allows RNA Regulatory Affairs personnel to evaluate Chains and individual Customers against statistical benchmarks that represent the average purchasing profile for the Customer group selected.
  - Purpose:
    - Evaluate Rx/controls purchases and base code purchases as part of Due Diligence processes.
    - Prioritize Due Diligence efforts.
    - Assist in determining statistical Red Flags that might require escalation for approval.

- *Customer Script & Dose Data Analyzer*
  Note: The ISMC Regulatory Affairs Team typically leverages Service First to run customer dispensing data through the Script & Dose Data Analyzer. However, RNA Regulatory Affairs personnel frequently process dispensing data through this tool without using Service First.
  - Definition – Analytical tool that enables Regulatory Affairs personnel to evaluate a pharmacy's dispensing patterns over a period of time to determine whether any potential statistical Red Flags exist.
  - Purpose:
    - Validate a customer's dispensing data for onboarding requests, TCRs, and other Due Diligence reviews as needed.
    - Compare dispensing data to purchase data in the Solver.

- *ISMC Standard Deviation Calculator*
  - Definition – Analytical tool that is refreshed monthly with the previous three months of purchase data, and which calculates how many standard deviations a registrant's monthly dose count and ratio are above the dose and ratio means of its servicing DC for any base code (DC-specific, works with all base codes).
  - Purpose:
    - Used by RNA Regulatory Affairs personnel as an additional geographic comparison.
    - May be leveraged in a variety of Due Diligence scenarios to identify potential statistical Red Flags.

- *Threshold Text Builder*
  - Definition – A tool designed to create threshold "Reason for Change" text in SAP that is consistent with data entry requirements of SOPs outlined in this Manual. It works with all base codes and "Reason for Change" text options, and can create text for single entries or a .csv file for a batch upload of multiple entries.
  - Purpose – To ensure all "Reason for Change" text in SAP is consistent with data entry requirements of SOPs outlined in this Manual.

- *Resources*
  - For further information:
    - See the Tutorial (PDF format) for the applicable CSMP Analytical Tool accessible on the Regulatory Affairs SharePoint site
    - Contact a member of the Regulatory Affairs Statistics & Analytics Team

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Appendix C – Business Intelligence Reports

Note: The following reports are located on the Regulatory Affairs SharePoint site, which can be accessed here.

Report Type	Report Name	Description
Sales	CSMP: Cust Purchase Detail Report	• All CSMP customer purchases & returns
Sales	CSMP: Cust Purchase Summary - Horizontal	• Summarizes CSMP customer purchases and returns per base code • Months run across the top in columns
Sales	CSMP: Cust Purchase Summary - Vertical	• Summarizes CSMP customer purchases and returns per base code • Months appear vertically in rows
Sales	CSMP: Cust Purchase Omit Detail Report	• Shows all "V" omits • Detailed report, but limited V omits • Omits by DC, Customer, DEA #, Family, Base Code
Sales	Sales History: Cust Suspicious Order Omits and Cancels	• All "V" omits and cancels (cancelled after SO create)
Sales	Sales History: BW Solver Input	• Customer purchases and ratios of "More Commonly Abused Drugs"
Accum.	MTD Accumulator Values	• Shows total monthly doses purchased by base code, monthly threshold, and percentage of base code already purchased and remaining dosages available.
Threshold	Customer Threshold Master Report	• Report current thresholds by customer
Threshold	Threshold Change Report	• Documents changes to thresholds over time • Shows user who made change and reason for change
Master Data	CSMP Item Master Report	• Displays items by base code along with a number of useful attributes
Master Data	Customer Master File Report	• Lists customers on CSMP by DEA #, expiration dates, DEA family, threshold warning, etc.

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Appendix D – Glossary of Terms

Term	Abbreviation	Description/Definition
Base Code	BC	Base codes are designated by the active ingredient contained in the medication. A single base code (e.g., oxycodone and hydrocodone) includes all generic and brand medications containing that active ingredient. *For a list of all base codes click here.*
BW Reports		Queries from SAP and generates web based reports.
Controlled Substance	CS	A controlled substance is a drug or chemical compound whose manufacture, distribution, sales and/or use are controlled by law.
Controlled Substance Monitoring Program	CSMP	McKesson's Controlled Substance Monitoring Program is a nationwide regulatory compliance program that is informed by diversion trends and our customers. The program is designed to implement and maintain effective controls against diversion, and detect and report suspicious orders to the DEA.
Chain Questionnaire		See Section 8.
Controlled Substances Act	CSA	The U.S. drug laws under which the manufacture, importation, possession, use, and distribution of certain substances is regulated. http://www.deadiversion.usdoj.gov/21cfr/21usc/ 21 U.S.C. United States Code, 2012 Edition. Title 21 - FOOD AND DRUGS. CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL.
CSMP Actions Tracking Tool		An internal tracking tool in which Regulatory Affairs records decisions regarding customer terminations and denials of onboarding requests for prospective customers.

Term	Abbreviation	Description/Definition
CSMP Red Flag		See Section 4.
Customer Script & Dose Data Analyzer		See Appendix B.
Drug Enforcement Administration	DEA	Lead agency for domestic enforcement of federal drug laws, and for coordinating and pursuing U.S. drug investigations abroad. www.justice.gov/dea
Due Diligence		See Section 4.
Investigative Report		See Section 8.
ISMC Customer Questionnaire		Regulatory Affairs document used to capture relevant information regarding the pharmacy's location, ownership, licensure and DEA registration information and business model.
Pharmacist in Charge	PIC	Pharmacist in Charge. Pharmacist knowledgeable about the practice and management of the pharmacy. Ensures proper licensure and certification of all pharmacy staff. Oversees the larger operation of the pharmacy in accordance with legal and regulatory requirements.
R Drive	R:\	McKesson Internal Network. Regulatory Affairs central document repository (or any successor repository)
SAP	SAP	McKesson's Enterprise Resource Planning (ERP) system. SAP contains customer transactional data.
SAP Business Warehouse	SAP BW	A suite of tools to report, analyze and interpret business data. In the context of the TCR processes, BW is used to report upon the customer's historical sales and threshold information useful in evaluating a threshold change request.
RNA Solver		See Appendix B.

Term	Abbreviation	Description/Definition
RNA Tracker		A tool currently housed on the RNA Regulatory Affairs SharePoint site that is used to log Due Diligence reviews.
State Board of Pharmacy		State pharmacy regulatory agency.
Start-up Pharmacy		A start-up pharmacy is a new RNA Customer that has not previous history of pharmacy business at the specific address where the Start-up pharmacist is located.
TCR Form		See Section 8.

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Appendix E – Guidance Documents, Tools, and Forms

Note: McKesson's internal network R:Drive is used as a central repository for many resources, guidance documents and forms used by Regulatory Affairs. The list below is not intended to be all-inclusive.

- Guidance Documents
  - For access to the following documents click here.
    - CSMP Red Flags List
    - Investigative Assessment Guide
  - For access to the following DEA Documents and Resources click here.
    - DEA Orangebook
    - Code of Federal Regulations (21 CFR §1300 to end)
    - Pharmacist's Manual
    - Chemical Handler's Manual
- Tools
  - For access to the following tools click here.
    - Script & Dose Data Analyzer
    - Threshold Text Builder
  - For access to the following tools click here.
    - RNA Tracker
    - RNA Due Diligence Tracker

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